

What is claimed is:

1. A formulation of amlodipine maleate where the formulation comprises a lubricant that does not contain alkaline-earth metal ions.

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2. The formulation of claim 1, where the alkaline-earth metal ion is magnesium.

3. The formulation of claim 1, where the alkaline-earth metal ion is calcium.

- 10 4. A formulation of amlodipine maleate comprising:

- a therapeutically effective amount of amlodipine maleate,
- a binder,
- a diluent,
- a disintegrant, and

- 15 - a lubricant that does not contain magnesium.

5. The formulation of claim 4, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

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6. The formulation of claim 5, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

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7. The formulation of claim 6, where the lubricant is hydrogenated castor oil.

8. The formulation of claim 6, where the lubricant is hydrogenated castor oil in combination with another lubricant.

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9. The formulation of claim 8, where the other lubricant is talcum.

10. The formulation of claim 7, where the pH is about 5.1.

10 11. The formulation of claim 7, where the formulation comprises less than 0.5% amlodipine aspartate.

12. The formulation of claim 7, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C and 75% relative humidity for one month.

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13. The formulation of claim 4, where the formulation comprises less than 0.5% amlodipine aspartate.

14. The formulation of claim 4, where the formulation comprises less than 3% amlodipine  
20 aspartate after storage at 100°C for 24 hours.

15. The formulation of claim 4, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C and 75% relative humidity for one month.

25 16. The formulation of claim 4, where the pH is about 5.0 to 5.4.

17. The formulation of claim 16, where the pH is about 5.1.

18. The formulation of claim 4, where the binder is selected from the group consisting of  
5 acacia, alginic acid, carbomer, carboxymethylcellulose sodium, dextrin, ethyl cellulose,  
gelatin, guar gum, hydrogenated vegetable oil, hydroxyethyl cellulose, hydroxypropyl  
cellulose, hydroxypropyl methyl cellulose, liquid glucose, maltodextrin, methylcellulose,  
polymethacrylates, povidone, pregelatinized starch, sodium alginate, microcrystalline  
cellulose, modified cellulose, and starch.

10 19. The formulation of claim 18, where the binder is selected from the group consisting of  
microcrystalline cellulose, modified celluloses, and povidone.

20. The formulation of claim 4, where the diluent is selected from the group consisting of  
15 calcium hydrogen phosphate ( $\text{CaHPO}_4$ ), anhydrous; lactose; and mannitol.

21. The formulation of claim 4, where the disintegrant is selected from the group consisting  
of alginic acid, carboxymethylcellulose calcium, carboxymethylcellulose sodium,  
croscarmellose sodium, crospovidone, guar gum, methyl cellulose, microcrystalline cellulose,  
20 polacrilin potassium, powdered cellulose, pregelatinized starch, sodium alginate, sodium  
starch glycolate type A, sodium starch glycolate B, and starch.

22. The formulation of claim 21, further where the disintegrant is selected from the group  
consisting of sodium starch glycollate (type A), sodium starch glycollate (type B), and  
25 crospovidone.

23. A formulation of amlodipine maleate comprising:

- a therapeutically effective amount of amlodipine maleate
- microcrystalline cellulose
- calcium hydrogen phosphate ( $\text{CaHPO}_4$ ), anhydrous
- sodium starch glycollate (type B)
- a lubricant that does not contain magnesium.

24. The formulation of claim 23, where the formulation comprises less than 0.5% amlodipine aspartate.

25. The formulation of claim 23, where the formulation comprises less than 3% amlodipine aspartate after storage at 100°C for 24 hours.

26. The formulation of claim 23, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C and 75% relative humidity for one month.

27. A formulation of amlodipine maleate comprising, by weight:

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|--|----------------|
| - amlodipine maleate   | about 2%-4%%   |
| - microcrystalline cellulose                                 | about 40%-70%  |
| - calcium hydrogen phosphate ( $\text{CaHPO}_4$ ), anhydrous | about 25%-50%  |
| - sodium starch glycollate (type B)                          | about 1%-3%    |
| - a lubricant that does not contain magnesium                | about 0.5%-7%. |

28. The formulation of claim 27, where the lubricant is two or more different lubricants that together represent about 0.5%-7% of the formulation, by weight.

29. The formulation of claim 27, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

30. The formulation of claim 29, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

31. The formulation of claim 30, where the lubricant is hydrogenated castor oil.

32. The formulation of claim 30, where the lubricant is hydrogenated castor oil in combination with another lubricant.

33. The formulation of claim 32, where the other lubricant is talcum.

34. The formulation of claim 31, where the pH is about 5.1.

35. A formulation of amlodipine maleate comprising, by weight:

- amlodipine maleate	3.21%
- microcrystalline cellulose	59.79-63.79%
- calcium hydrogen phosphate ( $\text{CaHPO}_4$ ), anhydrous	30.00%

- sodium starch glycollate (type B) 2 - 4%
- a lubricant that does not contain magnesium. 1 - 7%

36. The formulation of claim 35, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

37. The formulation of claim 36, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

38. The formulation of claim 37, where the lubricant is hydrogenated castor oil.

39. The formulation of claim 35, where the lubricant is two or more different lubricants that together represent about 0.5%-7% of the formulation, by weight.

40. The formulation of claim 39, where the lubricant is hydrogenated castor oil in combination with another lubricant.

41. The formulation of claim 40, where the other lubricant is talcum.

42. The formulation of claim 38, where the pH is about 5.1.

43. A method of making a formulation of amlodipine maleate where the method comprises combining:

- a therapeutically effective amount of amlodipine maleate
- a diluent
- 5       - a binder
- a disintegrant
- a lubricant that does not contain magnesium

where the resulting formulation of amlodipine maleate formed by so combining contains less than 0.5% amlodipine aspartate.

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44. The method of claim 43, where the formulation comprises less than 3% amlodipine aspartate after storage at 100°C for 24 hours.

45. The method of claim 43, where the formulation comprises less than 0.5% amlodipine aspartate after storage at 40°C and 75% relative humidity for one month.

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46. The formulation of claim 43, where the lubricant is two or more different lubricants that together represent about 0.5%-7% of the formulation, by weight.

47. The formulation of claim 43, where the lubricant is selected from the group consisting of colloidal silicon dioxide, powdered cellulose, starch, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, macrogol 6000, dimeticone, stearic acid, and talcum.

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48. The formulation of claim 47, where the lubricant is selected from the group consisting of sodium stearyl fumarate, dimeticone, macrogol 6000, hydrogenated castor oil, and stearic acid.

49. The formulation of claim 48, where the lubricant is hydrogenated castor oil.

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50. The formulation of claim 43, where the lubricant is hydrogenated castor oil in combination with another lubricant.

51. The formulation of claim 50, where the other lubricant is talcum.

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52. The formulation of claim 49, where the pH is about 5.1.

53. A method of treating and/or preventing hypertension, angina, or heart failure comprising administering to a patient in need thereof a therapeutically effective amount of a

15 pharmaceutical composition comprising:

- amlodipine maleate,

- a diluent,

- a binder,

- a disintegrant, and

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- a lubricant that does not contain magnesium,

where the pharmaceutical composition comprises less than 0.5% amlodipine aspartate.